

KNOWLEDGE, ATTITUDE AND PRACTICE OF PHARMACOVIGILANCE AMONG UNDERGRADUATE MEDICAL STUDENTS

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ABSTRACT

Pharmacovigilance (PV) is essential for ensuring drug safety by detecting, assessing, and preventing adverse drug reactions (ADRs). Despite its importance, ADR underreporting remains a global issue, with rates as high as 90–95%. Medical students, as future healthcare providers, play a crucial role in ADR reporting; however, gaps in their knowledge, attitude and practice (KAP) persist. This study aims to assess the KAP of PV among undergraduate medical students, identify barriers to ADR reporting and propose strategies for enhancing PV education. A cross-sectional study was conducted among 368 MBBS students at KMCH Institute of Health Sciences and Research, Coimbatore, Tamilnadu, India. A structured questionnaire assessed demographic details, knowledge (9 items), attitude (6 items) and practice (11 items) regarding PV. Data were analysed using IBM Statistical Package for the Social Sciences (SPSS) version 27.0. Among the participants, 60.9% were female and 42.9% were under 20 years old. While 77.7% correctly defined PV, only 53.8% recognised the role of clinical trials in detecting rare ADRs. Awareness of India's PV programme was moderate (66.8%), but only 45.1% had seen an ADR reporting form. Although 95.1% of students believed ADR reporting was necessary, only 5.7% had reported an ADR, highlighting a gap between awareness and practice. Key barriers included lack of training (66.6%), limited awareness of ADR monitoring centres (20.4%) and low utilisation of digital reporting tools (4.9%). Despite a positive attitude toward ADR reporting, practical engagement remains low due to insufficient training and regulatory awareness. Structured educational interventions can enhance PV practices among medical students.

Keywords: Pharmacovigilance, Medical students, Knowledge-attitude-practice, Drug safety, ADR reporting

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INTRODUCTION

Medication safety is a fundamental component of healthcare, and pharmacovigilance (PV) plays a crucial role in the detection, assessment, understanding and prevention of adverse drug reactions (ADRs) and other drug-related problems. ADRs contribute significantly to patient morbidity, mortality and increased healthcare costs, underscoring the need for effective monitoring and reporting systems. The World Health Organization (WHO) defines PV as “the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem” (WHO 2019). The effectiveness of PV systems depends largely on the active participation of healthcare professionals, including physicians, nurses and pharmacists.

Despite the recognised importance of ADR reporting, underreporting remains a major global challenge, with studies estimating that up to 90–95% of ADRs go unreported (Hazell and Shakir 2006). Medical students represent the future healthcare workforce, and their knowledge, attitude and practice (KAP) regarding PV are essential for fostering a culture of medication safety. Evidence suggests that early exposure to PV concepts and practical training positively influences future participation in drug safety monitoring (Katekhaye *et al.* 2017). However, several studies have reported that undergraduate medical students have inadequate knowledge regarding PV and ADR reporting (Bhatt and Kumar 2024).

Although undergraduate students often demonstrate positive attitudes toward ADR reporting, their level of practical involvement remains low, due to factors such as lack of awareness, insufficient training, fear of legal repercussions and uncertainty regarding what and how to report (Gupta *et al.* 2015). In many medical institutions, PV is introduced as a limited component of pharmacology and is often taught during the later years of the Bachelor of Medicine, Bachelor of Surgery (MBBS) curriculum rather than in the early phase of training. As a result, students may not fully understand the clinical relevance of ADR reporting or its role in patient safety and public health (Cheema *et al.* 2017).

Furthermore, the absence of structured, hands-on training in ADR reporting systems—such as the Pharmacovigilance Programme of India (PVPI)—limits students’ confidence and willingness to participate in PV activities (Kalikar, Dakhale and Shrirao 2020). Although medical students in India are permitted to report ADRs under PVPI, such reporting is typically carried out under faculty or clinician supervision, which may further restrict independent reporting practices at the undergraduate level.

Recent study evaluated PV knowledge and ADR reporting skills among undergraduate medical students using the Objective Structured Practical Approach (OSPA) model and identified notable gaps between theoretical awareness and practical reporting competence. Their findings underscore the need for competency-based, hands-on training in PV during undergraduate medical education (Sudha *et al.* 2025).

Another study reported that although undergraduate medical students and interns showed a favourable attitude toward PV, deficiencies in knowledge and ADR reporting practices remained significant (Bawa *et al.* 2025).

Key barriers to ADR reporting among undergraduate students include limited understanding of reporting protocols, insufficient motivation and self-confidence to identify and report ADRs and poor awareness of the clinical importance of PV.

While the increasing use of newer medications and complex treatment regimens highlights the importance of PV competence, expecting undergraduate students to demonstrate advanced practical skills may not be realistic when formal training is introduced at a later stage of the MBBS curriculum (Kalaiselvan, Thota and Singh 2016).

This study aims to evaluate the KAP of PV among undergraduate medical students, identify existing gaps and challenges, and propose strategies to enhance PV education and ADR reporting behaviour. The findings of this study may help in designing targeted educational interventions to improve ADR reporting practices among undergraduate medical students within the current institutional and curricular framework, and in similar academic settings

METHODOLOGY

After institutional human ethical committee approval, a cross-sectional study was conducted with Google Forms as the data collection tool. Data were collected using a structured, pre-validated questionnaire consisting of four sections: demographic details, knowledge (9 items), attitude (6 items) and practice (11 items) related to PV.

A pilot study was conducted among 30 undergraduate medical students who were not included in the final analysis. The pilot study assessed clarity, relevance and internal consistency of the questionnaire. Minor modifications were made based on feedback. Internal consistency of the questionnaire was assessed using Cronbach's alpha: knowledge domain ($\alpha = 0.78$), attitude domain ($\alpha = 0.81$) and practice domain ($\alpha = 0.74$). These values indicated acceptable to good reliability.

Following their informed consent, 368 responses from undergraduate students at the KMCH Institute of Health Sciences & Research in Coimbatore were collected. The questionnaire (Google Form) began with a description of the study's purpose and participants' willingness to participate. Details about the participants were kept private. The study did not include students who did not provide informed consent

Statistical Analysis

Data were analysed using IBM SPSS Statistics version 27.0. Descriptive statistics were expressed as frequencies, percentages and mean $\pm$ standard deviation. Questionnaire reliability was assessed using Cronbach's alpha. Associations between categorical variables were tested using the Chi-square or Fisher's exact test and comparisons of mean KAP scores were performed using independent *t*-tests and one-way ANOVA. Statistical significance was set at $p < 0.05$.

RESULTS

Among the 368 undergraduate MBBS students enrolled in the study, 42.9% were below 20 years of age, 31.3% were 21 years old and the remaining 25.8% were aged 22 years or above. In terms of gender, 60.9% of participants were females and 39.1% were males. Of the students, 51.4% were in third-year MBBS, 26.1% in final-year MBBS and 22.6% in second-year MBBS, with the total distribution accounting for 100% of respondents.

PV was defined appropriately in 77.7% of cases. Awareness regarding which ADRs need to be reported was observed in 85.6% of respondents. More than half of the students (53.8%) agreed that clinical trials are useful for identifying rare ADRs. A majority of respondents (82.3%) believed that healthcare professionals should be responsible for ADR reporting. While 72.8% of respondents were aware of the regulating body for ADR monitoring in India, only 39.7% could correctly identify it.

With regard to attitudes toward PV, 51.6% of students were aware of the PV committee at their institution and 66.8% were aware of the national PV programme. Only 45.1% had seen an ADR reporting form, and only 41.8% knew that the form is available in multilingual languages. Most respondents believed ADR reporting is necessary (95.1%) and supported formal training in PV (93.2%).

During clinical postings, ADRs were observed by 25.8% of participants; however, only 5.7% reported having documented or reported an ADR. Only 14.7% of respondents were aware of ADR reporting apps, and only 4.9% had used once (see Figure 1). The majority of respondents (77.2%) believed that ADR monitoring centres should be present in all hospitals, while 11.4% felt this should depend on the size of the healthcare facility and 5.4% believed such centres were not necessary in all hospitals.

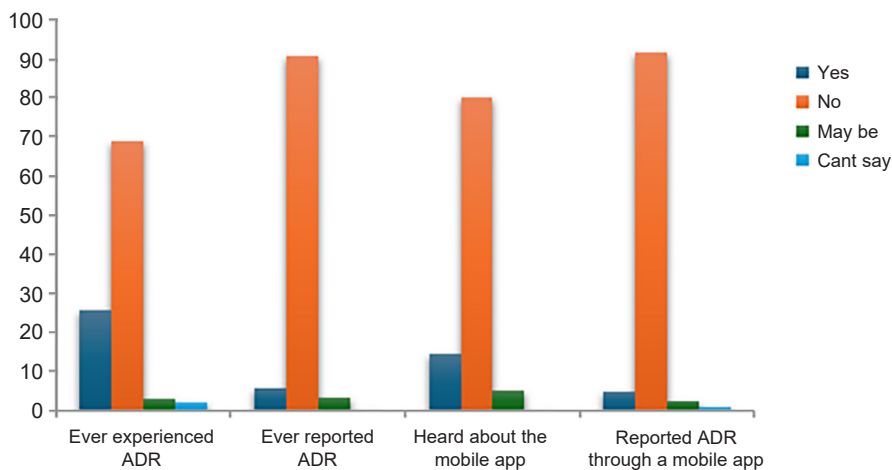


Figure 1: Practice towards ADR reporting

Analysis of knowledge scores showed that most students had a moderate level of understanding, with scores ranging from 5 to 6. Very limited knowledge was observed in a small proportion of students, with 0.8% scoring zero. On subgroup analysis, female students were more aware of hospital ADR centres (80.7% vs. 70.1%) and their obligation to report ADRs (85.7% vs. 77.1%). The likelihood of visiting the IPC website was higher among male students (21.5%) than among women (5.8%). No statistically significant association was observed between academic year and overall KAP related to PV (see Table 1).

Table 1: Knowledge and attitude towards ADR reporting.

Knowledge & Attitude Questions	Yes (%)	No (%)	May be (%)	Can't say (%)
Do you know about the existence of a PVPI?	66.8	23.4	9.3	0.5
Is there any PV committee in your institute?	51.6	7.9	34.0	6.5
Have you ever seen the ADR reporting form?	45.1	47.8	6.6	0.5
Do you know that the ADR form is available in multilingual?	41.8	42.7	15.2	0.3

(continued on next page)

Table 1: (Continued)

Knowledge & Attitude Questions	Yes (%)	No (%)	May be (%)	Can't say (%)
Do you know any nearby ADR monitoring centres in your area?	20.4	68.5	8.1	3.0
Do you know that a separate form is available for ADR due to vaccination	39.1	50.8	9.3	0.8
Have you attended any CME/ Workshop in PV?	9.5	86.7	3.5	0.3
Have you ever been trained on how to report ADRs?	33.4	56.5	8.5	1.6
Have you ever visited the IPC website and seen the drug safety alerts?	12.0	81.4	5.5	1.1
Do you think reporting ADRs is necessary?	95.1	1.9	2.7	0.3
Do you think it's necessary to include PV at undergraduate level?	89.1	4.1	6.5	0.3
Do you think PV should be taught in detail to healthcare professionals?	93.2	2.4	3.8	0.6
Do you think ADR reporting is a professional obligation for you?	71.2	16.8	10.4	1.6
Do you motivate patients to report any reactions caused after usage of drugs?	91.0	1.9	5.2	1.9

DISCUSSION

The current study evaluated MBBS students' PV KAP, with the findings reflecting broader systemic and curricular influences rather than individual shortcomings. Instead of reiterating numerical outcomes, this discussion focuses on interpreting the underlying reasons for the observed gaps and their educational implications. Although a higher proportion of participants were female, this demographic trend mirrors national and global patterns and is unlikely to independently influence PV competence (García-Abeijon *et al.* 2023).

While most students demonstrated basic theoretical awareness of PV, this understanding was largely conceptual and not accompanied by practical application, consistent with findings from other Indian medical institutions (Putri *et al.* 2024). Limited recognition of the role of clinical trials in identifying rare ADRs suggests that PV concepts are not sufficiently integrated into early clinical reasoning, highlighting deficiencies in preclinical exposure (Alomar *et al.* 2020).

Awareness of the regulatory framework for ADR monitoring was moderate; however, detailed understanding of regulatory structures and institutional roles remained limited, a finding consistent with previous studies reporting similar deficiencies among medical students (Othman *et al.* 2017).

Lower awareness of institutional PV committees compared with national programmes indicates limited visibility of hospital-based PV activities. Inadequate familiarity with ADR reporting forms and their multilingual availability further reflects insufficient hands-on exposure, as similarly reported in earlier studies (Gideon, Asthana and Bisht 2024).

Limited participation in PV workshops and continuing medical education represents a missed opportunity for developing practical competencies. Importantly, the low rate of ADR reporting should not be interpreted as inadequate performance, as ADR reporting in India is primarily the responsibility of registered medical practitioners, pharmacists and nurses. Undergraduate medical students are generally expected to participate only under supervision, making independent reporting unrealistic.

The strong endorsement for structured undergraduate PV training and near-universal agreement on the importance of ADR reporting indicate high student receptiveness. This suggests that the primary barrier lies in curricular structure rather than student motivation (Ahuja and Sharma 2010).

Support for establishing ADR monitoring centres in all hospitals aligns with WHO recommendations aimed at improving patient safety. However, differing opinions regarding the necessity of ADR monitoring centres suggest incomplete understanding of their role across healthcare levels, as seen among the minority who felt that hospital size should determine their need.

Moderate knowledge scores not only indicate baseline awareness but also emphasise the scope for improvement through structured and repeated training. Observed gender-based differences may reflect disparities in academic engagement or access to digital PV resources rather than inherent differences, as suggested in previous literature (Lopez-Gonzalez, Herdeiro and Figueiras 2009; Sidhu *et al.* 2023).

The absence of a significant association between academic year and PV competence suggests that exposure is neither progressive nor reinforced across MBBS training. This contrasts with some previous studies reporting better knowledge among senior students (Hans and Gupta 2018; Farooq *et al.* 2021). These findings underscore the need for a vertically integrated PV curriculum spanning preclinical and clinical phases.

Despite positive attitudes, practical engagement remains limited, largely due to restricted roles and inadequate supervised exposure. Educational interventions should focus on early introduction, supervised case-based learning, and clear role delineation for students in ADR identification rather than independent reporting. Greater emphasis on institutional PV units, digital tools and formal orientation to reporting systems may further strengthen engagement. Overall, curriculum-level reform rather than isolated awareness initiatives is likely to have the most sustainable impact.

CONCLUSION

This study demonstrates that undergraduate medical students possess a reasonable level of theoretical awareness of PV and a positive attitude towards ADR reporting; however, this knowledge does not consistently translate into practical competence or active participation. The findings indicate substantial gaps in students' familiarity with institutional PV structures, ADR reporting tools and regulatory processes, reflecting limited curricular emphasis and inadequate hands-on exposure. Although most students recognised the importance of ADR reporting and supported formal training, their actual involvement in ADR identification and reporting was minimal, likely influenced by delayed curricular introduction and restricted reporting roles for undergraduate students.

Overall, the results suggest that the observed deficiencies are systemic rather than individual and underscore the need for curriculum-level reform. Early and longitudinal integration of PV into the MBBS curriculum, supervised practical exposure during clinical postings and improved visibility of institutional PV mechanisms may help bridge the gap

between knowledge and practice. These measures could strengthen medication safety awareness among medical students and better prepare them to contribute effectively to PV activities in their future professional roles.

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